Questions and Answers from PGA Webinars and the 2015 Trade Symposium

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U.S. Customs and Border Protection

Questions from PGA Webinars and the 2015 East Coast Trade Symposium

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I. General Questions Related to Multiple PGAs

A. Client Reps:

1. *How do I find out who my CBP client rep is?*

Information on the roles of the Client Representatives and to find out who your Client Representative is may be found on cbp.gov on Page 11 of the ACEopedia. Please reference the following URL: http://www.cbp.gov/document/report/aceopedia.

B. FTZ:

1. *What is the status of PGA integration with FTZ Cargo Release and Entry Summary?*

Development of PGA requirements for goods entering a foreign trade zone is scheduled to begin in summer 2016 as part of the "e214" refactoring work.

When cargo is entered into an FTZ, it goes through an e214 process. The e214 is the electronic entry document used to request entry of merchandise into the FTZ. Currently, an FTZ online module is used to manage the e214 process for cargo entering FTZs. The functionality of this module needs to be integrated into ACE, and this is referred to as "e214 refactoring." This will allow for ACE processing for all cargo entering an FTZ, including cargo with PGA requirements.

II. PGA Specific Questions

A. Animal and Plant Health Inspection Service (APHIS)

a. APHIS Core

1. *Is participation in each pilot limited? How many are participating in each?*

APHIS does not limit the number of participants or pilots. However, the CBP Client Representatives will work with APHIS and the participant to arrange a time for each pilot.

2. *We file entries for cut flowers. When we go to ACE cargo release, will we be able to electronically transmit the PPQ data set only, or do we need to sign up for pilot for PPQ?*

At this point, the Trade cannot begin submitting PGA data without first going through CERT testing and then scheduling a pilot with their client reps. We encourage the Trade to follow the steps on the APHIS website that will guide them to the pilot phase. There are 2 documents on our website under "APHIS Pilot Projects" that will guide them through what they need to do.

APHIS Core consists of four programs: *Plant Protection and Quarantine (PPQ), *Veterinary Services (VS), *Biotechnology and Regulatory Services (BRS), and *Animal Care (AC). The Lacey Act Program falls within PPQ but is identified separately and has its own PGA Message Set Information Guide. However, only PPQ, VS, and Lacey Act are participating with the piloting activities at this time.

**Note, different acronyms are used for APHIS programs within the PGA message sets. Plant Protection and Quarantine is referred to as APQ, Veterinary Services as AVS, Biotechnology and Regulatory Services as ABS, and Animal Care as AAC.*

3. *Just to confirm, brokers still have to upload through DIS for any permits or forms, correct?*

Only the APHIS 2006 will be uploaded via DIS. TheVS16-6a Permits (USDA permit to Import Controlled Materials, Organisms, and Vectors) and PPQ import permits will no longer be provided in paper and do NOT need to be uploaded through the DIS. The broker should use the PGA Message Set to provide the permit number along with other unique identifiers required by the message set. A copy of the permit should travel with the shipment in case there are additional questions by the inspector, but the goal is to have admissibility decisions made using the PGA message set. Please refer to the slide in the PowerPoint (APHIS Core webinar on 12/09/2015) which indicates which forms are submitted through DIS.
Link to PowerPoint given on 12/09/2015:
http://www.cbp.gov/sites/default/files/documents/BIEC%20-%20APHIS%20ACE%20Update%20-%20December%209%202015.pdf

4. *Will APHIS eventually accept message sets alone without the need to submit images of permits using DIS?*

Yes, see response to question II A(a)(3).

5. *At the time of inspection by USDA do we need to present the import permit?*

It will depend upon the specific commodity being imported. Please refer to question II A(a)(3).

6. *When do you expect CFIA Certificates to come on line, i.e. to not require paper submission?*

APHIS is working closely with all our trading partners to establish the electronic certification process for government to government certifications. Work is ongoing with CFIA but we do not yet have an expected date for that functionality to be available.

7. *Are we still going to have to present copies of the Permit to Import Plant and Plant Products at the physical inspection of fresh produce?*

All paperwork required for entry should accompany the shipment of fresh produce in case the officer inspecting the shipment has questions. However, CBP officers will be able to pull up the permit in ACE using the data collected through the PGA message set. All government to government certifications will still be required in paper.

8. *Since we are transmitting PGA data, are we still required to present hard copy 9540 forms for USDA inspection?*

Form 9540 is a Food Safety Inspection Service (FSIS) form. Form 9540 is a Food Safety Inspection Service (FSIS) form. FSIS has provided this response:
If the broker/filer is providing the FSIS, PGA message set data in the ACE entry, then FSIS does NOT require the paper copy of FSIS Form 9540-1.

9. *Will the USDA Statements for animal product permits now be accepted electronically instead of an original needed at the port?*

If you are referring to the STAT that animal products collect, that will come through the Document Image System (DIS). If you are referring to health certificates (i.e. government to government certifications) they will still be required in paper.

b. APHIS Lacey Act

1. *The Lacey act shouldn't change too much, just enter the same information as before, no need to upload docs, right?*

The Lacey Act requirements have not changed. A disclaimer code is available for filers who filed in LAWGS or do not need to file a declaration.

2. *Can filers use the disclaim reason code "D" when providing a hard copy of 505 upon import? Secondly, what validations will be in place in ABI to enforce this?*

The use of a PPQ Form 505 to file a declaration involves mailing the form to APHIS Lacey Act Program at the address identified in the instructions section of the form. CBP does not require a PPQ Form 505.

3. *I believe I saw a schematic of the forms that can be submitted to DIS. Does this cover all the PGA forms, and does it show which are paper or electronic, and are mandatory?*

Yes, that specific and comprehensive information is available on the www.CBP.gov website. The document accessed by the below link lists forms/data by PGA and specifies which information is acceptable via DIS:
http://www.cbp.gov/document/guidance/ace-november-1-pga-forms.

The following link will take you to the ACE CATAIRs, or technical requirements:
http://www.cbp.gov/trade/ace/catair.
Under the *Supporting Documents* tab, there is a section for the DIS. Under the *PGA Message Set* tab, there is information on the submission (including requirements) of electronic information (per agency), much of which was previously processed in paper forms.

Within the APHIS presentation (APHIS Core webinar on 12/09/2015), it explains what documents must be submitted and in what format each is required.

Link to 12/09/15 webinar presentation:
http://www.cbp.gov/sites/default/files/documents/BIEC%20-%20APHIS%20ACE%20Update%20-%20December%209%202015.pdf.

The Lacey Act does not utilize DIS documentation.

4. *Please explain responsibility of signature certification.*

The PGA (APHIS) requires a signature at the bottom of the Lacey Act Declaration certifying to the truthfulness and correctness of the information provided in the declaration. The name provided as the signatory for the certification statement (e.g. broker, importer) should be the party accepting responsibility for the truthfulness and correctness of the data provided for the declaration. The same applies when submitting the Lacey Act declaration via ACE.

5. *Is there a list of Lacey Act HTS codes?*

The USDA APHIS Lacey Act Program webpage provides a link to the HTS codes enforced by the Lacey Act Program, or follow the link below: https://www.aphis.usda.gov/plant_health/lacey_act/downloads/ImplementationSchedule.pdf.

6. *Please clarify that the Lacey and APHIS Core are separate PG message sets. They are not done the same way.*

Yes, there are two separate and distinct message set guides for APHIS. One is for the Lacey Act Program, and one is for the APHIS Core. They do have different required data elements. However, all of the required information can be submitted through ACE at one time.

c. Live Animals

1. *Pending*

d. Animal Products

1. *Pending*

B. Environmental Protection Agency (EPA)

(Questions from the BIEC EEC EPA Webinars on 12/08/15 and 12/15/15)

Please note that answers may not be exactly the same as provided verbally during the webinars. The questions and answers have been grouped by topic category. Duplicate questions between the two webinars have been consolidated

a. Chemicals Subject to the Toxic Substances Control Act (TSCA)

1. *Will the Blanket TSCA Declaration program still exist with the Automated Commercial Environment (ACE)?*

No. CBP will publish a proposed rule in 2016 to allow electronic submission of TSCA certification statements in the Automated Commercial Environment (ACE), and will propose to eliminate the TSCA blanket certification process. The new electronic reporting capability that will be available in ACE for all ports nationwide means an individual paper blanket TSCA certification for a specific port is no longer needed.

2. *What is the timing for EPA to process the PGA filing, in relation to the CBP variable release window for each of the different modes of transport? For example, for a sea freight shipment, if we file the entry with PGA/EPA data 10 days prior to arrival at the port of entry, will EPA process that PGA filing immediately and potentially provide a "may proceed" ten days prior to the arrival, or will that wait until the CBP variable release window of 5 days prior to arrival?*

The EPA PGA message set entry filings will be processed in ACE when they are filed by the importer. If the filing passes the automated checks and any EPA review, a 'may proceed' message may be provided at that time. EPA strongly encourages early filing so any corrections to the filing needed in order to receive a "may proceed" message to be provided prior to arrival and in some cases prior to loading onto a conveyance. This could be well in advance of the five day CBP release window for ocean shipments. The EPA is currently working with several large importers to file prior to loading onto a conveyance for ocean and rail shipments.

3. *Have the HTS numbers for TSCA been identified, and will they be flagged?*

No, EPA has not flagged HTS codes primarily because HTS codes do not clearly identify TSCA-related chemical substances. The EPA believes that a review of the HTS codes the Trade uses in TSCA filings will be beneficial to confirm the appropriateness of flagging HTS codes. In this regard, the EPA encourages Trade to provide information to EPA on the HTS codes used for TSCA entries. The EPA has already received some HTS code lists used by brokers for TSCA certifications and would like to see others. Becoming familiar with the HTS codes being used by Trade will better assist the EPA with flagging HTS codes in the future.

In is important to emphasize that the importer or his authorized agent is ultimately responsible for knowing when a TSCA certification must be filed. A checklist for TSCA certification filings can be found at: http://www.epa.gov/sites/production/files/2015-03/documents/checklist.pdf. The Toxic Substances Control Act Hotline (tsca-hotline@epa.gov) is available to answer general questions about TSCA import and export requirements. The TSCA Hotline operates Monday through Friday, from 8:30 a.m. to 5:00 p.m. Eastern time. Call (202) 554-1404. FAX requests for documents are received every day, at all times, on (202) 554-5603.

4. *What is the difference between testing in the CBP Certification environment and testing in production?*

EPA strongly encourages the Trade to make test filings, including joint filings, in the CBP Certification environment prior to making production filings (i.e., live filings). Testing should not be done in production. It should be done in the certification environment. Testing in CBP's Certification environment allows the filer to make sure they are providing the correct information in the correct format in the correct records. It also familiarizes filers with the messages they may expect to receive, what they mean, and what actions or corrections may be needed.

Filing in the Certification environment also helps the EPA and CBP double check that the filing is being processed correctly, and the proper status and messages are being provided. The EPA and CBP have found that filing in the Certification environment streamlines an equivalent live filing for a shipment in production.

The EPA PGA message set TSCA pilot will go live for filings in production when CBP publishes a Federal Register Notice (FRN) announcing the initiation of the TSCA pilot. Electronic filings for TSCA using the PGA message set should not be made until the pilot FRN is published.

5. *Is EPA currently active in the ACE Certification environment?*

EPA is very active in the ACE Certification environment and strongly encourages all filers to test in the Certification environment. EPA will schedule calls for the first production filings for actual shipments after testing has been completed in the CBP Certification environment by the filer.

6. *Who do we contact at EPA to get set up for testing TSCA filings in the CBP Certification environment?*

Contact your client rep and Roy Chaudet at EPA at chaudet.roy@epa.gov

7. *How and when would the necessary data be filed for entries into FTZs? Are there any participants in the TSCA pilot who import into FTZs?*

EPA and CBP are looking into this question, and will take into account what also works for other PGAs.

We do not currently have participation in the pilot from importers who make entries into FTZs, and would welcome such participation.

8. *Are the edits in the ACE Certification environment the same as the live environment?*

For EPA-related filings, the business rules in the Certification environment ARE THE SAME as for production filings.

9. *When testing in the CBP Certification environment, can information from a previous shipment be used?*

We encourage you to test data that are equivalent to what you would expect to be filed for a live production filing. It does not need to be the exact data you would use for a live production filing for that shipment. You can also use data from previous shipments if you expect to file something similar in the future. Depending on the commodity (e.g., pesticides, vehicles and engines) we will likely need to provide the tester with certain LPCO (license, permit, certificate, or other) numbers that we know will pass validations to complete testing.

10. *If you use a software service provider, and it tests its software through the certification process, is a customs broker using the software still required to certify and test through EPA?*

Yes, because although the software may have passed all of the tests, the actual filer needs to know how to use the software to file the correct information in the correct format. Brokers who do not have a certification account are encouraged to work with their software vendor to do a few tests in the certification environment that are equivalent to what would be expected in a live production filing for a shipment.

Alternatively if you are unable to test in the Certification environment, you can provide a version of your filing to EPA via email to review BEFORE you file in production.

11. *Can the TSCA certification form be filed in ACE via the Document Imaging System (DIS)?*

There is no TSCA positive or negative certification form. TSCA certifications will have to be provided in the PGA message set. ACE will do an automated check, and if the correct information is provided, the filing will receive an automated "may proceed" message. If the required information is not provided, the filing will receive a "reject" message.

12. *Will the EPA be preparing a supplemental "Guidance" for the trade on what data elements the importer will be required to submit at time of entry, as well as what additional data elements will be optional or elements consistent with EPA suggested Best Practices for expedited review and release processing?*

The Updated EPA Supplemental CATAIR Guidelines and PGA Message Set Samples were posted on 12/23/2015 and are available to the public via the following links:

- EPA Supplemental CATAIR Guidelines V7.0 November 17, 2015
  http://www.cbp.gov/trade/ace/catair
  http://www.cbp.gov/document/forms/epa-supplemental-catair-guidelines

- EPA PGA Message Set Samples Pilot Programs V7.0 November 17, 2015
  http://www.cbp.gov/trade/ace/catair
  http://www.cbp.gov/document/guidance/epa-pga-message-set-samples-pilot-programs

13. *Can the TSCA positive or negative certification be changed to a simple YES and NO?*

Depending on the software vendor, these screens may be set up with a simple yes/no for positive and negative TSCA certification statements. Keep in mind that a specific code must be provided in the ABI filing (usually done by the vendor software) that identifies the specific TSCA positive and negative certification statements.

14. *Is a hard copy document (e.g., blanket statement) or wording on the CI required to be submitted into DIS to effect release?*

TSCA certifications will only be provided via the PGA message set, not the DIS. This allows automated checks to ensure that the correct information has been filed.

15. *Can the TSCA negative certification statement be disclaimed?*

No, a negative TSCA certification is still required to be filed. A disclaimer is used when the commodity is not subject to reporting a negative or positive TSCA certification. A checklist for filing TSCA certification can be found at: http://www.epa.gov/sites/production/files/2015-03/documents/checklist.pdf

b. Pesticides

1. *How do I get in the FIFRA pilot for filing Notices of Arrival (NOAs)?*

Contact your client rep and Roy Chaudet at EPA at chaudet.roy@epa.gov

2. *If a NOA requires a revision, can the revision be made through the PGA message set (at time of entry) or maintained as a separate process (with EPA directly)?*

Yes, the ACE filing with the NOA (formerly EPA Form 3540-1) can be updated prior to arrival. The EPA encourages early filing, so any corrections to the filing needed to receive a "may proceed" message can be provided prior to arrival and in some cases prior to loading onto a conveyance. We expect to do a pesticides-specific webinar in March 2016 that can provide an overview and answer additional questions.

3. *Does the NOA need to be signed off by the EPA with an original signature, as is done today?*

No. The NOA will be filed electronically with the CBP entry information through the ACE single window.

4. *How will NOA submissions work with FTZ admissions? For example, will consumption entries utilize an entry number reference that will be used at time of NOA submission and at time of entry?*

EPA and CBP are looking into this question, and will consider what also works for other agencies.

5. *So, even the information from pesticide NOAs will be electronically transmitted?*

Yes, the data elements in a NOA will be filed electronically in ACE with the CBP entry information. The on-product label will need to be filed in the Document Image System (DIS) before the entry filing.

6. *For unregistered pesticides, will comments noted in Boxes 18 and 19 flow through the PGA message set or reside in the original NOA?*

Information in boxes 18 and 19 from the form 3540-1 will be included in the electronic filing using the PGA message set. All NOAs for the importation of unregistered pesticides must be reviewed by EPA import coordinators. When a NOA for an unregistered pesticide is filed in ACE, the importer will receive an "under review" notification, and an EPA import coordinator will review the filing and provide feedback where needed.

e. Vehicles and Engines

1. *If not participating in the EPA pilot, please describe the hybrid filing process for non-road vehicles and engines after 02-28-2016 to obtain an EPA release.*

Please note that EPA is <u>not</u> one of the three federal agencies subject to the February 28, 2016, deadline for electronic filing. The agencies affected by the February 28, 2016, deadline are: the Animal and Plant Health Inspection Service (APHIS) in the Department of Agriculture; the Food and Drug Administration (FDA); and the National Highway Traffic Safety Administration (NHTSA) in the Department of Transportation.

You may continue to file non-road V&E forms after February 28th the same way you file them now, unless/until CBP publishes a rule stating otherwise.

C. Food and Drug Administration (FDA)

a. General Questions:

1. *We are a pharmaceutical importer in the Boston area - who, how, and where would we communicate within FDA? Our local FDA office is already too busy to respond to our inquiries.*

Please contact ACE_Support@fda.hhs.gov to participate in the pilot or for questions about ACE and FDA's requirements.

2. *When will the FDA requirements be "locked down," so the Trade & their software providers can move ahead with testing and filing?*

FDA considers their requirements to be outlined. Any additional updates are refinements or clarifications, until such a time that new regulatory requirements indicate the need for further changes. Clarifications are added to help explain the requirement to trade. One change that is planned as a result of information and experiences gained during the pilot is the addition of a PG field (PG60) to accommodate longer identifying information (name, address, point of contact), if additional room is needed. These final changes will be ready to implement early to mid-February.

3. *If a broker doesn't have all the information, will you still be able to transmit the entry?*

Entries that are missing mandatory or conditional data elements will be rejected by CBP. Please contact FDA at ACE_Support@fda.hhs.gov to learn the requirements or request an orientation for how to file an ACE entry.

4. *Does BRD cover food?*

BRD stands for Biologic Regulated Device. This is not food.

5. *Is the "deliver to party" the same as the ultimate consignee?*

Yes, for all practical purposes; FDA is looking for the entity fitting the definition of ultimate consignee for CBP.

6. *How far in advance can we file FDA Information for ocean shipments?*

For the purposes of FDA Prior Notice, this information must be filed no less than 2 hours before arrival for Trucks, 4 hours for Air or Rail, and 8 hours for Ocean. Otherwise, for the purposes of admissibility, FDA entry information may be filed as far in advance as allowed by CBP.

7. *How will CBP/FDA use the Point of Contact information? Is that essentially who will receive notices of action and other compliance-related inquiries? (Should it be someone at Corporate vs. the receiving site?)*

Notices of action are sent to the importer of record. The point of contact for the entry should be the filer/broker. The Point of Contact information will be used by the FDA office reviewing the

entry to obtain additional information regarding the specific entry, as necessary. This will expedite the admissibility process by being able to discuss any entry issues immediately. The Point of Contact should have clear knowledge of the shipment information. With respect to any Notices of FDA Action, FDA will continue to provide this documentation to the importer of record, consignee, and filer/broker.

8. *Will there be a webinar for the food industry?*

The FDA held a Food Webinar on January 19, 2016.

Here is the link to the webinar recording:
https://dhs.adobeconnect.com/_a956619115/p9gpzqc4n49/?launcher=false&fcsContent=true&pbMode=normal

Here is a link to the slide presentation:
http://www.cbp.gov/sites/default/files/documents/Final%20FDA%20ACE%20FOODS%20Webinar%20Powerpoint.pdf

9. *Please elaborate on PG30. Is it expected that all shipments will provide this data element? Or, is this only for items that require advance notice of arrival?*

All FDA entries require one or more data elements to be submitted under PG30/anticipated arrival information.

10. *What if we have multiple intended end uses in one shipment? What if we do not know the intended use at the time of import?*

The importer and/or other responsible parties should advise the filer what the intended use of the products are to the best of their knowledge when offered for import. A product with multiple intended uses should be declared on separate FDA lines.

11. *What training is in place for the FDA employees in regards to ACE? Many times they rely on us (the broker) to inform them on what the latest update is.*

The FDA continually provides internal briefings, updates and discussions to Agency field staff in various forums regarding ACE, its impact, and requirements. While ACE changes the way brokers/filers transmit information electronically, the entry review process at FDA remains the same.

12. *When will we be able to file stand-alone BTA? Currently we process stand-alone on cargo discharging West Coast ports for cargo moving in bond. Once on the rail, we send the entry.*

Stand-alone prior notice filings are currently being accepted as part of the FDA ACE pilot.

13. *Our company Imports capital equipment that requires climate control and clean room environment. We have found that if data is not exactly accurate, there may be a delay, (at minimum) 2 days. This could damage the equipment. Currently, we move equipment to a*

clean-room warehouse until the FDA clears it. How can we avoid FDA delays through the Single Window, aside from getting the data exactly correct?

As in the current ACS world, correct and complete data will expedite the review and processing of FDA entries. While ACE changes the way brokers/filers transmit information electronically, the entry review process at FDA remains the same. With the enhanced FDA Supplemental Guide and data requirements, with correct and complete data there should be far fewer document requests and technical follow-up with local FDA. If filers require assistance or have questions regarding specific data elements, contact ACE_Support@fda.hhs.gov.

b. FDA Pilot:

1. *If we sign up for the pilot, do all our FDA entries need to be filed in the pilot?*

You may file entries in ACE at your own pace, while continuing to file other entries in ACS until the dates set forth by CBP.

2. *When will the FDA PGA pilot be complete?*

At this time, the FDA pilot is ongoing until further notice.

3. *Will it still be in pilot up until the FDA deadline for filing in ACE, or will the pilot be complete before then so that FDA can be filed as normal without being in pilot?*

The FDA ACE pilot will continue until further notice from CBP and FDA.

4. *Are all the fields which are mandatory for the pilot also going to be mandatory in production?*

The mandatory, and conditional when indicated, data elements outlined in FDA's *Supplemental Guide* (http://www.cbp.gov/document/guidance/fda-supplemental-guide-release-16) are the information FDA requires for ACE (production) entries.

Additional PGA technical information can be found here: http://www.cbp.gov/trade/ace/catair.

5. *You mentioned that with a pilot it is appropriate to change the data requirements. The concern is if the pilot is not a valid test, the required data elements will change when ACE goes live for FDA filing. Why not make the test mirror the go live system?*

The data requirements outlined in the FDA's Supplemental Guide are the data elements required for an ACE entry. While there may be minor tweaks, the expectation is that the Supplemental Guide (after the pilot is terminated) will look very similar to the Supplemental Guide as it currently exists. That being said, the data requirements outlined in the FDA Supplemental Guide will be dynamic in that changes will be made as new laws are passed and regulations written/published to implement those laws, for example, the Foreign Supplier Verification Program (FSVP) importer identification requirements outlined in the FSVP section. For more information, contact ACE_Support@fda.hhs.gov

c. Facilty Establishment Identifier (FEI)/Data Universal Numbering System (DUNS):

1. *If we are already providing the complete name and address of the manufacturer/shipper, why is the FEI mandatory?*

FEI or DUNS # are optional. Name and address of all parties is mandatory. Providing a DUNS or FEI may expedite processing.

2. *Since the DUNS# is part of the registration process and should be in the FDA database, why is that being asked for in the entry process when an FEI is being provided?*

DUNS numbers are equivalent to the registration numbers for drugs. This is not true of other FDA products. FEI or DUNS # are optional for all commodities.

3. *Why does the name and address for each party need to be provided if we transmit the FEI and/or DUNS number?*

Name and address is mandatory. DUNs or FEI is optional (but encouraged) and asked as a two-step verification for the entity. This is necessary to verify the party through the two-step validation.

4. *Are DUNS #s required for all FDA regulated products? Is it mandatory?*

FEI or DUNS numbers are optional. To obtain or query a DUNS (for free), visit www.fdadunslookup.com.

Name and address of all parties is mandatory. Providing a DUNS or FEI may expedite processing.

5. *When you say that providing a DUNS or FEI "may expedite" FDA review, does that mean it's impossible to get a systematic "may proceed" (i.e., without manual review) if it's not provided? Or, can we still get automated may proceeds with name/address alone?*

There are many variables associated with FDA's screening process, including the overall risk of the product. Choosing not to provide a DUNS or FEI does not mean it will be impossible to achieve a system may proceed, although in certain scenarios, providing an FEI or a DUNS may expedite review.

6. *Should importers expect delays post the FDA filing deadline from the additional FDA-ACE filing data requirements, specifically re: DUNS#? How long? What rate of compliance is the FDA expecting from foreign manufacturers with a DUNS#?*

FDA encourages early participation in the pilot so that filers are familiar with their software updates, FDA's requirements, and the end-to-end ACE process. Appropriate testing should mitigate the risk of delays. At this time, DUNS numbers are optional for all commodities. Filers must provide name and address for all entities, a DUNS or FEI number is optional but encouraged.

d. 5 Day Review Period:

1. *Currently we have to cancel and re-submit entries if FDA information wasn't submitted, or the information submitted is grossly incorrect. In the new system, will we be able to re-submit the entry to FDA after the 5 day review period, or will we have to cancel it?*
   What about land border entries where the filer keys in the entry, and the shipment crosses the same day, i.e. within a few hours, which happens all the time at land border crossings

Updates/edits to entries will not be permitted if the cargo is within five-days of arrival in the United States, unless the entry is rejected by CBP or FDA. If changes need to be made to the entry during that time, the entry will need to be cancelled and re-submitted. Regardless of the mode of transportation, entries submitted the same day (or same hour) as arrival are included in the five-day lock down.

For example, an update may be made if entry data is transmitted seven days prior to arrival. Once the timeframe hits the five days prior to arrival, CBP sends the data to FDA, and no further edits may be made once the entry is accepted by CBP and the FDA.

e. Other Systems:

1. *Will ITACS go away with ACE?*

No, ITACS should be used to provide further verification or information when requested by FDA. Once DIS incorporates line-level functionality, FDA expects to work with CBP to transition to DIS so that any additional documentation only needs to be submitted one time to 1USG.

2. *Will ITACS be phased out?*

FDA will continue to use ITACS until DIS allows for line-level functionality; however, the current plan is to incorporate the amenable ITACS functionality into DIS when the DIS functionality allows so that Trade will have a secure data portal to electronically upload documentation for all PGAs as part of the cargo release process.

3. *With ACE implementation, will PREDICT be decommissioned?*

No, FDA will continue to process/screen data as it does today using OASIS and PREDICT.

4. *When is DIS expected to have line level functionality?*

Currently CBP has not provided a date as to when such functionality will be available.

f. HTS Codes:

1. *How do you determine when a product item flags for FDA or FCC?*

Through their account with CBP, brokers/filers will have access to the HTS codes and the associated OGA or, under ACE, PGA flag(s.) One HTS code representing a product item may be associated to one or more PGA flags. For more information, check with your CBP ABI Client Representative.

2. *Can you create a guidance or supplement document for items that may be subject to FDA? For example, items that are in heading 9013, it says that it may require FDA, also for heading 9016.*

It is important to note that the U.S. International Trade Commission publishes and maintains the Harmonized Tariff Schedule in its various forms, however U.S. Customs and Border Protection is the only agency that can provide legally binding advice or rulings on the tariff classification of articles offered for import into the U.S. There are many tariff code headings and sub-headings under each chapter, such as 9013 or 9016 under chapter 90. Thus, many FDA-regulated products and non- FDA-regulated products may be encompassed by one chapter or under a heading/sub-heading. It is the responsibility of the importer of record to determine if the items being offered for import are regulated by the FDA and/or any other PGA; however, the intended use of the product often determines whether the product is regulated by FDA. FDA's website provides guidance to help with the import process at www.fda.gov/ForIndustry/ImportProgram. If further assistance is needed, questions can be directed to your local import office; you can email FDAImportsInquiry@fda.hhs.gov, or you may call (301) 796-0356.

HTSUS Heading 9013 encompasses "Liquid crystal devices not constituting articles provided for more specifically in other headings; lasers, other than laser diodes; other optical appliances and instruments, not specified or included elsewhere in this chapter; parts and accessories thereof". This is a good example of a tariff heading that encompasses FDA-regulated articles and articles that are not regulated by FDA. The FDA does not regulate liquid crystal devices (LCD), however the FDA does regulate many different types of radiation-emitting products. The FDA's website http://www.fda.gov/Radiation-EmittingProducts/default.htm contains information and guidance documents for radiation-emitting products.

HTSUS Heading 9016 encompasses "Balances of a sensitivity of 5 cg or better, with or without weights; parts and accessories thereof". FDA may regulate an analytical balance under FDA product code 75JQL, but FDA does not regulate commercial scales such as those used for shipping purposes, body weight measurement, etc. Once again, FDA's website www.fda.gov is a great source for information.

g. Foreign Supplier Verification Program (FSVP)

1. *What additional data elements will be required for FDA submissions, and what impact will the Food Safety Modernization Act (FSMA) Foreign Supplier Verification Program (FSVP) requirements have on these submissions?*

In addition to the data elements currently listed in the FDA Supplemental Guide, FDA anticipates requiring the identification of the FSVP importer at the time of entry, unless exempted, under the Food Safety Modernization Act (FSMA) Foreign Supplier Verification Program (FSVP). When required at entry, the FSVP importer will need to be identified by its name, physical address, email address, and unique facility identifier number. For more information on FSVP and identifying the FSVP importer at entry, please review the final rule and "Am I subject to FSVP?" on FDA's FSVP website: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm.

h. Foreign Trade Zone (FTZ):

1. *I am an FTZ operator that is filing weekly entry. I have heard that FDA may be collecting data at time of entry summary and cargo release. Is that true? When will the FDA requirements for PGA be finalized for zones.*

For the purposes of weekly estimates offered for import from a foreign trade zone (FTZ), FDA will continue to process the weekly entry estimate filed at the time of cargo release, as in the current ACS environment. In future phases, FDA may receive electronic data from the entry summary for audit purposes.

2. *On a weekly 3461estimate for a zone, I don't have all of the information that is required by FDA as I will be producing and packaging the product throughout the week. What should I enter on my estimate?*

As indicated in the FDA supplemental guide, "If reporting only one level of packaging, show the total quantity for the line and report that as level 1." Thus, should the responsible parties only have an estimated piece count for the weekly estimate, the Packaging could be transmitted as XX PCS for XX pieces in PG26.

i. API/AOC/Codes:

1. *How will bulk APIs be product coded?*

Building an FDA Product Codes for ACE/ITDS is the same as it has been with ACS. The Process Indicator Code (PIC) portion of FDA's Product Code identifies the product as an API or a finished dosage form. An API will have either an "S" or a "T" PIC.

2. *API's must show producers for an end user. Does that include contract manufacturers?*

It would depend on the Intended Use Code. If the API is being imported to be manufactured into a finished drug under an approved application, then the firms would be required to be identified per the approved application.

3. *Is the list of A of C codes in the guide a full list?*

All valid codes for FDA are included in the Supplemental Guide. Affirmation of Compliance and Intended Use Code information on FDA's websites will also be updated to reflect the amendments in the Supplemental Guide.

3. *Is FDA or CBP going to enforce intended use codes and/or AoC codes if they are incorrect?*

Yes. Missing or incorrect data, including Intended Use Codes and Affirmations of Compliance codes with required elements will prompt error messages.

4. *Will FDA be populating the AoC for the last line of the chart on page 226?*

Affirmations of compliance are not required for those import scenarios.

5. *Any special codes for ambient temperature? If so, is it a mandatory field?*

FDA does not require temperature, the temperature related data elements in the PG25 record are optional fields.

j. Devices:

1. *Is the Trade Name/Brand Name field marked as mandatory when a device is registered? We are finding this field blank in the database, but FDA is rejecting entries for this not being provided.*

Since fiscal year 2013, all proprietary (brand) names that a device is marketed under in the U.S. must be included on the listing. At least one proprietary name is required in order to complete the listing process. If the proprietary name is deemed confidential, it would not be releasable (not be in the registration and listing database – filers would need to obtain that information from the importer/lister).

For every medical device entry, the filer needs to provide the brand name(s) under which the imported products are being marketed in the US, as listed by the manufacturer. It may be on the invoice. If the brand name is not confidential, it will also be in the public registration and listing website:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
(Brand name is called *Proprietary Name* in the database)

Otherwise, the filer will need to work with its shipping partners to obtain the brand name(s).

Additional information regarding brand names:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm318796.htm#brand

2. *What is the difference between FDA importer and Device initial Importer?*

According to 21 CFR 807 (g), the *Device Initial Importer* is defined as :
"(g) Initial importer means any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package."

FDA's Regulatory Procedures Manual defines *Importer of Record* as the following:

"The individual responsible for assuring that imported goods are in compliance with all laws affecting the importation. While the importer may authorize others to carry out certain tasks such as filing, the importer of record holds the bond and is ultimately responsible for the entry." Refer to 19 CFR 101.1 for the CBP definition of the importer.

3. *What will be the risks if the IOR decides to use the standard import intended use code for all of their importations?*

Brokers must declare accurate information in accordance with 19 CFR 111.32. Supplying inaccurate information may result in delays in entry processing and may also result in other regulatory compliance actions taken by FDA and CBP.

4. *What is the conditional Affirmation LWC?*

LWC stands for Electrode Lead Wire Or Patient Cable. To review a description of this affirmation of compliance and what FDA product codes are applicable visit: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm248321.htm

5. *What will be the intended use code for toothbrushes?*

If the toothbrushes are for consumer use, 081.001 (Consumer use a medical device) should be supplied. If the toothbrushes are for another use, refer to FDA's Supplemental Guide for the list of intended use codes applicable to medical devices.

k. Radiation Products:

1. *How do you know if a product emits radiation?*

If you know the product code, you can verify if it is radiation emitting here: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm

Any product that contains an electronic circuit and generates any kind of radiation is an electronic product that emits radiation. X radiation (x-rays), microwaves, radio waves (radiofrequency (RF)), laser, visible light, sound, ultrasound, and ultraviolet light are a few examples of the many types of radiation-emitting electronic products. Diagnostic x-ray systems, laser products, laser light shows, and microwave ovens are a few examples out of the many different electronic products that emit radiation. Legal definitions of the terms "electronic product radiation" and "electronic product" are located in the Federal Food, Drug, and Cosmetic Act, Chapter 5, Subchapter C - Electronic Product Radiation Control. http://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/default.htm

2. *What are the additional data elements required for radiation emitting products in ACE vs ACS?*

The data elements for radiation emitting products are outlined in FDA's Supplemental Guide and include: Program and Processing Code, Intended Use, Product Code, Country of Manufacture, Brand Name, Description, Manufacturer, Shipper, Importer, Delivered To Party, Point of Contact, Affirmations of Compliance (if any apply), Value, Quantity, Packaging, and Anticipated Arrival Date and Time.

For additional specificity, please refer to: http://www.cbp.gov/sites/default/files/documents/FDA%20Supplemental%20Guide%20Release%202.4%20for%20posting-%20FINAL.pdf

3. *Since a code can't be used twice, what about devices that require BOTH a PMN and a PMA?*

PM# is the new Affirmation of Compliance code for PMA and PMN. One product should not have two PM#'s. If there are two PM#'s there should be two separate products declared on two FDA lines.

l. Cosmetics:

1. Pending

m. Tobacco Products:

1. Pending

D. National Highway Traffic Safety Administration (NHTSA)

1. *Will the NHTSA HS-7 form still be required in a paper/electronic format to be maintained for 5 years? Or, does the new electronic data transmission take the place of also generating the actual form?*

   In lieu of having to present paper to the CBP official at the port of entry, the HS-7 data has been programmed into the ACE PGA data set, and the DIS allows for the submission of HS-7 supporting documents. In the PG22 Record, the broker certifies that the entity making the HS-7 declaration [Code 946] has a copy of the document by entering a [Y] at Position 5. This was drawn from CBP's Partner Government Agencies, ACE ABI CATAIR. For the PG22 Record, the CATAIR states: "A code of Y (yes) indicating that the importer has a copy of a document (contract, PGA permission letter, etc.) needed to import a product that is under a government agency jurisdiction. No other code is accepted." Also in the PG22 Record, the broker certifies that the "data or the signature is on file" by entering a [Y] at Position 25, and the document was signed on a valid date. The CATAIR states: "A code of Y (yes) indicating that the entity certifies the data or the signature is on file. No other code is accepted." We believe that the intent of the CATAIR is consistent with NHTSA's desire that the basis for making the electronic HS-7 declaration is valid and to identify the entity who is making the declaration. Whether the Customs broker will make the declaration to the government on the basis of a documented telephone call, email, letter, or paper copy of an HS-7 is the Customs broker's decision.